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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ALEXANDRIA, VA 22314				
EXAMINER				
SHOMER, ISAAC				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,988

Applicant(s)

LEINO ET AL.

Examiner

ISAAC SHOMER

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 19-22 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 19-22 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 15 December 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 19-22 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner notes that the term "acid dissociation constant" for an acid HB (wherein B is the conjugate base) is normally defined by one of ordinary skill in the art as the equilibrium constant of $K_a = \frac{[H^+][B^-]}{[HB]}$, and not pK_a , which is the negative base ten logarithm of K_a . Example of an acid with a K_a that is near applicant's claimed range is nitric acid, which has a K_a of 28.¹ As it appears that applicant is using the term "acid dissociation constant" to refer to pK_a , which is contradictory to how it is normally used by one of ordinary skill in the art, the

¹ <http://chemed.chem.purdue.edu/genchem/topicreview/bp/ch17/ph.php>, Seventh page.

claim is indefinite as applicant has not redefined the term in the specification. See MPEP 2173.05(a)(III).

If, purely *en arguendo*, applicant is using the term "acid dissociation constant" to mean " pK_a ", claim 28, which is drawn to the elected species still appears to be indefinite because it is unclear whether cis-urocanic acid has any pK_a values in the range of 6.7 to 7.4. In support of this, the examiner evidences Mohammad et al. (Photochemistry and Photobiology, 6(2), 1999, pp. 115-135), page 116 right column, first sentence in section labeled "Prototropic Equilibria of UA" which teaches pK_a values of 3.5, 5.8 And 13 for urocanic acid.

For the purpose of examination under the art, the elected species of cis-urocanic acid will be examined.

Claims 19, 20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites the limitation "said reaction" in the method of claim 16. There is insufficient antecedent basis for this limitation in the claim. Claim 16 fails to recite the term "said reaction;" as such, there is no antecedent basis for such a reaction. For the purposes of examination, the examiner interprets claim 19 as if it reads "The method of claim 16 wherein a reaction involving activation of cells of the innate immune system is inhibited."

Claims 16, 19-22 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. The term "non-dissociated form" of claim 16 is indefinite. The specification does not define this term, and one of ordinary skill in the art would have been unable to have determined the difference between a "dissociated form" versus a "non-dissociated form." For example, the examiner is unable to determine whether a deprotonated carboxylic acid is considered a "dissociated form." As the elected species contains both a carboxylic and an imidazole, it is unclear whether a zwitterionic species (i.e. a species with a deprotonated carboxylate and a protonated imidazole) would be considered non-dissociated.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 19, 20, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cormier et al. (US Patent 5,995,869).

Cormier et al. (hereafter referred to as Cormier), columns 11-12 Example 2, teaches a method of transdermally administering (column 12 line 7) a formulation comprising tetracaine hydrochloride and cis-urocanic acid (column 11 lines 66-67) using electrotransport to guinea pigs (column 12 line 19), wherein the pH of said formulation is below 5 (column 12 lines 4-6). In a separate embodiment, a pH of about 8 is taught, as of Cormier, column 13 line 3. Cormier suggests a pH of greater than 5 for administering an anionic drug, as of Cormier, column 7 lines 2-5. The purpose of administering cis-

urocanic acid appears to be the prevention of sensitization of the skin or mucosa during drug delivery, as of Cormier, column 4 lines 39-42, and cis urocanic acid is also taught for the purpose of inhibiting "contact sensitization"² as of Cormier, column 7 lines 20-25. "Contact allergy" and "allergic contact dermatitis" is also taught, as of a phase in the process of sensitization, as of Cormier, column 2 lines 61-65 and column 3 lines 10-12 (hypersensitization is believed to be synonymous with "allergy").

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables specifically cis-urocanic acid at various pH ranges, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro., 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not

² "Contact Sensitization" of the prior art, is understood to read of "contact hypersensitivity reactions" of

seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients specifically cis-urocanic acid at various pH ranges, from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

Cormier suggest the use of pH ranges of greater than 5 for administering an anionic drug, as of Cormier, column 7 lines 2-5. While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cormier et al. (US Patent 5,995,869) as applied to claims 16, 19, 20, and 28 above, and further in view of Wille et al. (US Patent 5,912,010).

Cormier et al. (US Patent 5,995,869, hereafter referred to as Cormier), columns 11-12 Example 2, teaches a method of transdermally administering a formulation

comprising cis-urocanic acid using electrotransport wherein said cis-urocanic acid is used to inhibit skin hypersensitivity reactions.

Cormier is silent as to whether the method of administration is systemic, local, or is neither systemic nor local.

Wille et al. (hereafter referred to as Wille) teaches administration of agents for the treatment of allergic contact dermatitis (as of Wille, column 4 lines 10-13), wherein said composition may be administered in the form of lotions and creams³, as of Wille, column 4 lines 34-36. Such a formulation wherein cis-urocanic acid is the adverse skin reaction preventing or treating agent is taught by Wille, column 10 lines 40-45, Example 3.

It would have been prima facie obvious for one of ordinary skill in the art to have administered urocanic acid locally in the form of a cream or a lotion. This is because the administration of urocanic acid to the skin in such a form is known to be suitable for the intended use of preventing adverse skin reactions such as contact sensitization. Use of a known technique (local administration with a cream or a gel) to improve a known method (the delivery of cis-urocanic acid), to have predictably inhibited contact sensitization is prima facie obvious. See MPEP 2143, Exemplary Rationale C.

Conclusion

³ Lotions and creams are considered to be local administration, as of the instant specification, page 8 lines 20-24

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612